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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,780

07/02/2007

Eugen Kolossov

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06/05/2009

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EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT

PAPER NUMBER

1632

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,780	<b>Applicant(s)</b> KOLOSSOV ET AL.	
	<b>Examiner</b> MARCIA S. NOBLE	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-81 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 15, 16, 26, 40-42, 45, 49, and 70-75, drawn to an in vitro tissue formation method and resultant co-culture and tissues.

Group II, claim(s) 1-16, 26, 40-42, 45, 49, 70-75, drawn to an in vitro cardiac tissue formation method.

Group III, claim(s) 17, drawn to in vivo method of transplanting cells/tissues to a damaged area and the cells or tissues being transplanted.

Group IV, claim(s) 18-20, drawn to a method of improving cardiac function comprising culturing ES cell comprising a resistance gene and reporter gene under the control of a cardiac specific promoter in conditions to allow for the differentiation of the ES cells into cardiocytes, isolated the cardiocytes, and transplanting the cardiocytes into an infarcted area of the heart.

Group V, claim(s) 21-25, 27-42, and 70-75, drawn to a method of obtaining tissue comprising transfecting multipotent cells and isolating cells.

Group VI, claim(s) 21-25, 27-42, 70-75, drawn to a method of obtaining tissue comprising transfecting pluripotent cells and isolating cells.

Group VII, claim(s) 50, drawn to a method of transplanting tissue.

Group VIII, claim(s) 51-56, drawn to a method of improving cardiac function comprising transfecting ES cells, culturing ES cells into cardiomyocytes, fibroblasts, or endothelial cells, eliminating non-differentiated cells, forming cardiac tissue, and transplanting said tissue.

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Group IX, claim(s) 43, 44, 47, and 48, drawn to cells or cell aggregates comprising a nucleic acid encoding a resistance gene and reporter gene operably linked to a tissue specific promoter.

Group X, claim(s) 45-48, drawn to tissues comprising cells comprising a nucleic acid encoding a resistance gene and reporter gene operably linked to a tissue specific promoter.

Group XI, claim(s) 46-48, drawn to an organ comprising cells comprising a nucleic acid encoding a resistance gene and reporter gene operably linked to a tissue specific promoter.

Group XII, claim(s) 57, drawn to a vector comprising a nucleic acid encoding a resistance gene and reporter gene operably linked to a cardiac specific promoter.

Group XIII, claim(s) 58, drawn to cells comprising a nucleic acid encoding a resistance gene and reporter gene operably linked to a cardiac specific promoter.

Group XIV, claim(s) 59 and 60, drawn to an array comprising cells.

Group XV, claim(s) 59 and 60, drawn to an array comprising tissues.

Group XVI, claim(s) 61, drawn to an apparatus for analyzing arrays.

Group XVII, claim(s) 62-75, drawn to a method of obtaining a test substance capable of influencing cell development or tissue structure comprising contacting a test sample with cells and determining the phenotypic response to the test substance.

Group XVIII, claim(s) 62-75, drawn to a method of obtaining a test substance capable of influencing cell development or tissue structure comprising contacting a test sample with tissues and determining the phenotypic response to the test substance.

Group XIX, claim(s) 62-75, drawn to a method of obtaining a test substance capable of influencing cell development or tissue structure comprising contacting a test sample with samples in an array and determining the phenotypic response to the test substance.

Group XX, claim(s) 76-79, 81, drawn to a method of manufacturing a drug.

Group XXI, claim(s) 80, drawn to a kit comprising a vector.

Group XXII, claim(s) 80, drawn to a kit comprising a multipotent cell and medium.

Group XXIII, claim(s) 80, drawn to a kit comprising a pluripotent cell and medium.

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Group XXIV, claim(s) 80, drawn to a kit comprising recombinant nucleic acid molecules.

Group XXV, claim(s) 80, drawn to kit comprising standards.

Further, if Applicant elects group I, a further election of a specific cell type is required for claim 9. This is a restriction requirement and not an election of species.

If group II is elected, group I and II will be rejoined.

The inventions listed as Groups I-XXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

In the instant case both situations A and B apply.

A) The special technical feature as defined in claim 1 is a co-culture of ES cells derived cells that are allowed to integrate or align to form a tissue-like structure. The breadth of ES cell derived cells encompasses ES cell themselves, differentiating ES cells, or differentiated cells. The claims and specification do not specify that the first ES derived cell and the second ES derived cell can not be the same ES cell or be derived from the same ES cell. Therefore, the culture of multiple ES cells of the same origin or the co-culture of ES cells of the same origin that spontaneous differentiate into different cell types are encompassed by the limitations of the claims.

Rambhatla et al (US 6,458,589 B1 Patent Date:10/1/2002) disclose primate ES cells are allowed to differentiate into a mixed population of cells by forming embryoid bodies (col

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3, lines 15-18). This disclosure teaches the special technical feature because it teaches the co-culturing of ES cells, and ES-derived cells that produce a mix population of cells. The formations of embryoid bodies encompasses the limitations of allowing the cells to integrate and align into a tissue like structure.

Therefore, the instant invention lack unity because the prior art of Rambhatla et al discloses the special technical feature as disclosed in claim 1 and thus the special technical feature of the intention does not define a contribution over the prior art.

B) The instant claims encompass multiple products and method of use and make. A category encompassing multiple products is not a category that is defined as having unity of invention as discussed above. Thus, the instant claims also lack unity because the claims encompass a category of invention that is not consider to encompass unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/  
Primary Examiner, Art Unit 1632

Marcia S. Noble  
AU 1632